

REMARKS

In the Office Action mailed on January 3, 2007, the Examiner rejected claims 1, 2, 6-9, 11-24, 31, 34, 45, and 46 under 35 U.S.C. § 101 as allegedly claiming non-statutory subject matter; rejected claims 37-44 under 35 U.S.C. § 102(b) as allegedly being anticipated by Nuwayser (U.S. Patent No. 4,687,481); and indicated that claims 25-30, 32, 33, 35, and 36 are allowable.

By this Amendment, Applicants amend claims 37, 45 and 46. Claims 1, 2, 6-9, and 11-46 are currently pending in this application, with claims 1, 25, and 37 being independent.

As an initial matter, Applicants gratefully acknowledge the Examiner's indication of the allowability of claims 25-30, 32, 33, 35, and 36.

35 U.S.C. § 101 Rejection

Applicants respectfully traverse the Examiner's rejection of claims 1, 2, 6-9, 11-24, 31, 34, 45, and 46 under 35 U.S.C. § 101. Applicants do not necessarily agree with the characterization that "the scope of Applicant[s'] specification in [sic] defines the *tissue sheet as a suspension of cells or genetically engineered tissue* construct, which is in line with being constructed of living matter." But even assuming that the claimed "sheet of tissue," "cellular suspension," and "engineered tissue" are constructed of living matter, the Patent Office has long accepted claims directed to living organisms, including transgenic animals and skin grafts, for example. Authority for the patentability of living matter comes from the Supreme Court. The Court has held that, where a patentee "produced a new bacterium with markedly different characteristics from any found in nature[,] ... [h]is discovery [was] not nature's handiwork, but his own;

accordingly it [was] patentable subject matter under § 101.” *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). Thus, living matter is not, in itself, unpatentable.

Moreover, according to the Court of Appeals for the Federal Circuit, “[o]f course, a process, machine, manufacture, or composition of matter employing a law of nature, natural phenomenon, or abstract idea may be patentable even though the law of nature, natural phenomenon, or abstract idea employed would not, by itself, be entitled to such protection.” *In re Alappat*, 33 F.3d 1526, 1542 n.18 (Fed. Cir. 1994) (*en banc*). In accord are the Patent Office’s November 22, 2005 Interim Guidelines for Examination of Patent Application for Subject Matter Eligibility. Page 19 of those Guidelines states that a claim satisfies Section 101 requirements if it is “a practical application of [an] abstract idea, law of nature, or natural phenomenon.” (Emphasis in original.) The Guidelines also state that a claimed invention that “transforms’ an article or physical object to a different state or thing” satisfies Section 101.

In this application, even if “sheet of tissue,” “cellular suspension,” or “engineered tissue” include natural phenomena and/or living matter, the claims including those elements are practical applications of those natural phenomena/living matter. Each of the rejected claims is a combination claim that includes additional elements such as a substrate and a protective liner having certain features. The combination of elements is not directed to anything found in nature. As the Supreme Court has stated, in determining eligibility “for patent protection under § 101, [a patentee’s] claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements.” *Diamond v. Diehr*, 450 U.S. 175, 188 (1981). Considering claims 1, 2, 6-9, 11-24, 31, 34, 45, and 46 as a whole, they are thus patentable subject matter under 35

U.S.C. § 101. Applicants therefore request reconsideration and withdrawal of the Examiner's rejection of claims 1, 2, 6-9, 11-24, 31, 34, 45, and 46.

35 U.S.C. § 102(b) Based on Nuwayser

Applicants respectfully traverse the Examiner's rejection of claims 37-44 over Nuwayser under 35 U.S.C. § 102(b). Applicants have amended independent claim 37 in order to advance prosecution of this case. Amended independent claim 37 recites, among other things, "an implant of tissue." The Examiner contends that the macroporous membrane 14 corresponds to the claimed "implant of tissue." Nuwayser, however, nowhere suggests that macroporous membrane 14 includes tissue. Amended independent claim 37 is thus allowable over Nuwayser. Claims 38-44 all depend from independent claim 37 and are allowable for at least this reason.

To the extent that the claimed implant of tissue may comprise living matter, Applicants direct the Examiner to the response to the Examiner's rejections under 35 U.S.C. § 101, above.

Conclusion

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, and/or drawings in this Amendment, it is to be understood that Applicants are in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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